PSJ17 Exh 9

From: Pyfer, Andy
To: Patel, Pranay P
Sent: 6/16/2006 7:04:48 PM
Subject:
Attachments: OVF Commercial Needs_Leadership Meeting 07_21_05.ppt

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File Provided Natively

ACCELANYL Commercial Needs

US Pharmaceutical Leadership Meeting

May 18, 2005

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Presentation Overview

- Current ACTIQ Challenges
- Commercial Timeline
- ACCELANYL Key Commercial Issues
- ACCELANYL Critical Success Factors
- Organizational Implications of CSFs
  - Objectives & Strategies

Current ACTIQ Challenges

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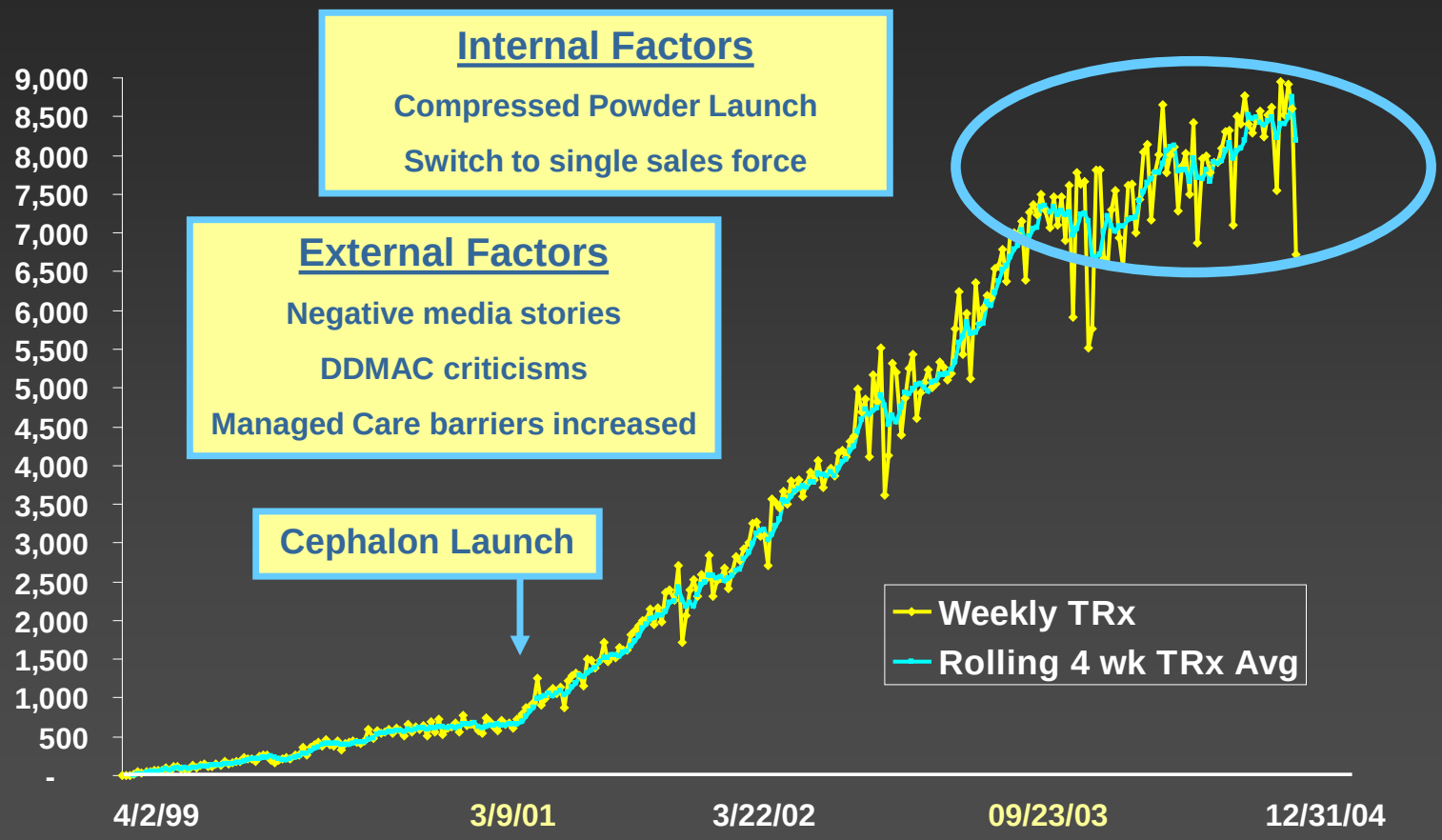
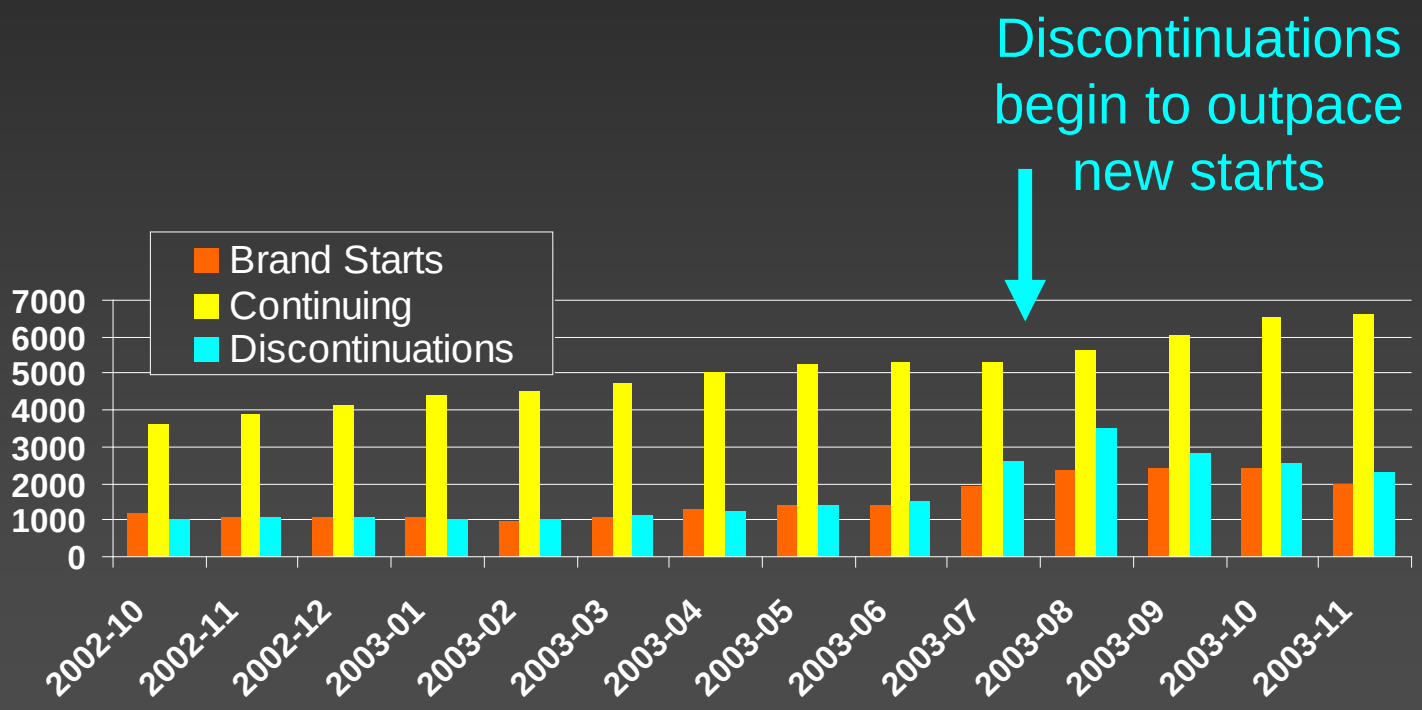
ACTIQ Challenges



Source: IMS

Discontinuations Spike with Compressed Powder Launch



Source: IMS NPA

“Egg” Research

Identify Drivers & Barriers

Conducted: September 2004

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"Egg" Research

- Objective
  - Talk to "good eggs" and "bad eggs" to identify barriers and drivers to ACTIQ usage
- Who
  - 47 physicians
    - Long-term writers who are writing more
    - Long-term writers who are writing less
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Source: Qualitative research N = 47, Leo Gibney Associates, Sept. 2004

"Egg" Research Summary

- Key Drivers to ACTIQ usage
  - Efficacy – rapid onset of action
  - Patient acceptance / satisfaction
  - Low side effect profile

- Key Barriers to ACTIQ usage
  - Reimbursement
  - Abuse and addiction concerns
  - Nothing new

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ACTIQ Chart Study

Assess Prescriber Characteristics

Conducted: Q4 2004

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- Objective
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Source: IMS Chart Audit,12/04

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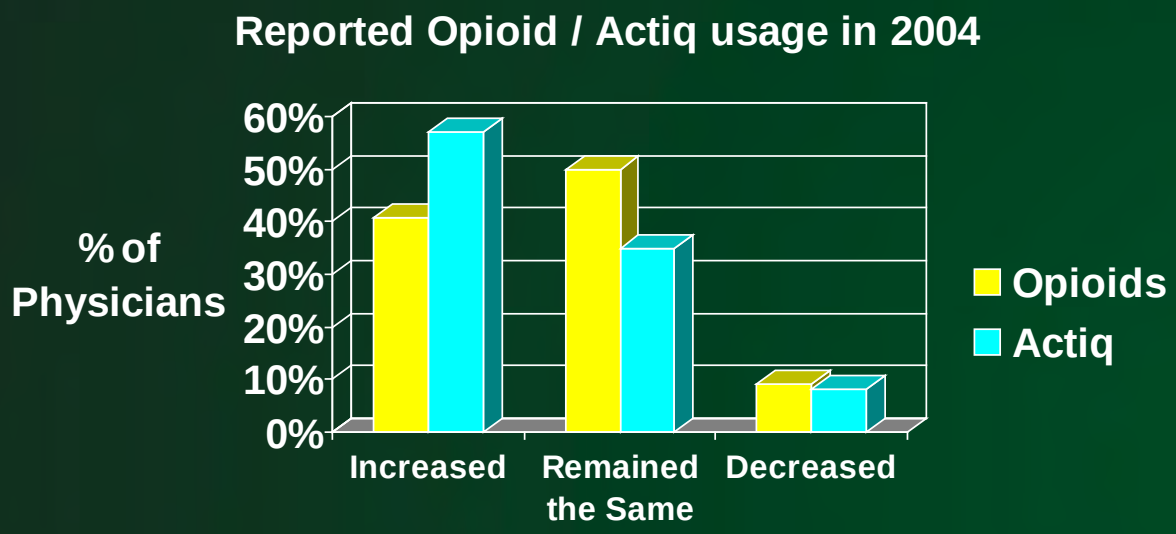

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Commercial Timeline

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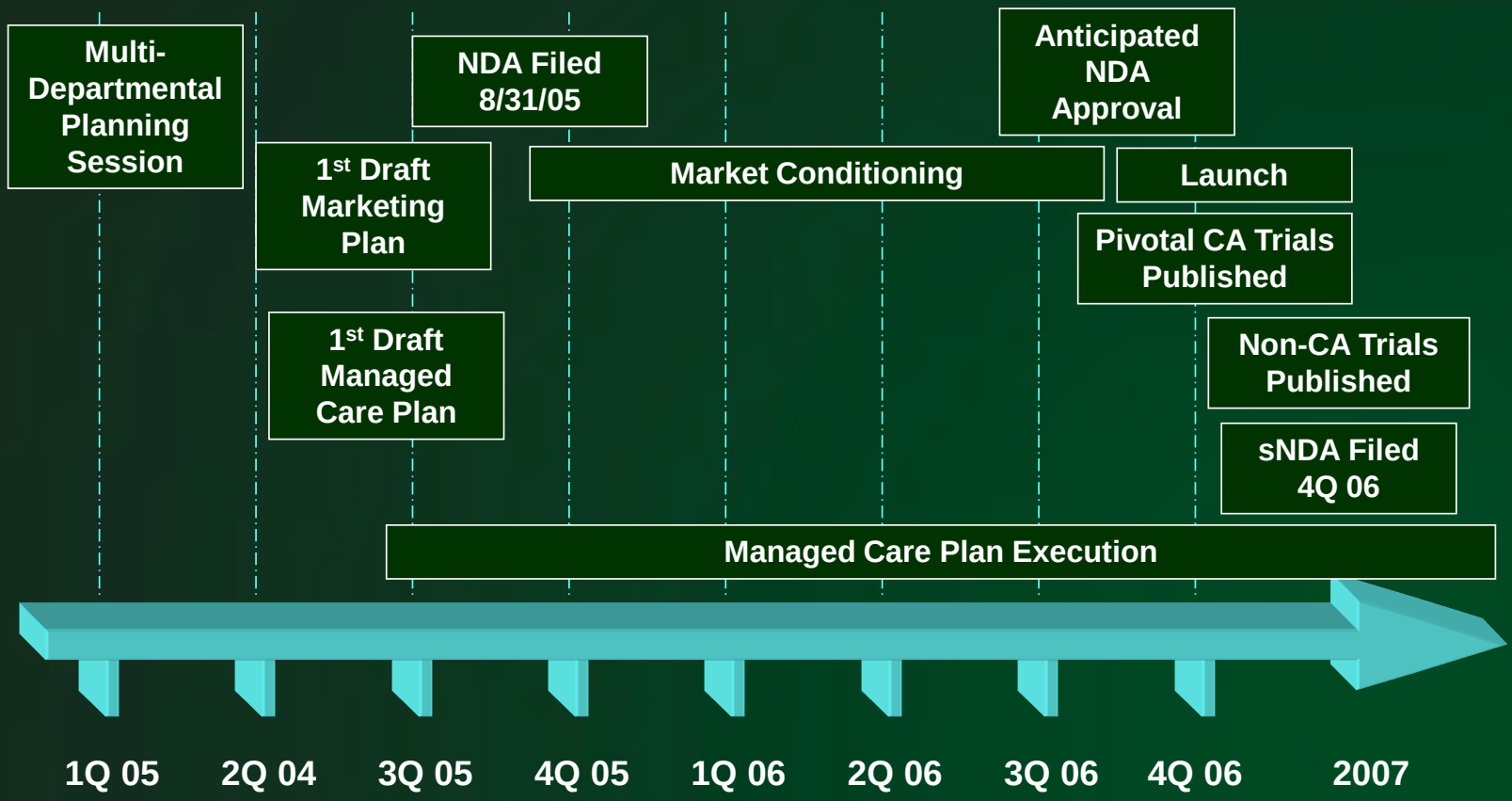
Commercial Timeline



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ACCELANYL Key Commercial Issues

Consensus Gained at Commercial Planning Meeting 1/26/05

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ACCELANYL Commercial Planning Session

- Departments represented
  - Marketing (Pyfer, Terifay)
  - SciComm (Hughes, Patel)
  - WWPP (Richardson – BST Lead)
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  - Publications (Riotto)
  - Health Economics (Wang)
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  - Follow-up has involved Sales Force Management (Cunningham, Carnohan)
- 2nd ACCELANYL Planning Meeting – Today 12-5pm

Factors of a Successful Switch

- Adequate time to establish the successor brand prior to the availability of the generic version of the precursor brand
- Level of clear and meaningful differentiation between the precursor and the successor
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- Comprehensive managed care strategy to drive favorable reimbursement
- Extensive patient database that will enable DTP correspondence

Key Commercial Issues

- Absence of time to convert ACTIQ prescribers
- Appropriate resources dedicated to effectively convert ACTIQ prescribers within first 90 days post launch
- Anticipated unfavorable reimbursement status
- Limited awareness and understanding of appropriate diagnosis & treatment of BTP
- Limited KOL relationships
- Challenging selling/marketing environment requiring sophistication & expertise

ACCELANYL Critical Success Factors

Consensus Gained at Commercial Planning Meeting 1/26/05

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ACCELANYL Critical Success Factors

1. Successfully convert ACTIQ loyalists to ACCELANYL adopters within the 90 day period
2. Continue to develop BTP market by increasing awareness and understanding of BTP and its optimal treatment (ROOs)
3. KOLs support ACCELANYL as an effective treatment option for BTP
4. ACCELANYL is clearly differentiated from ACTIQ and other BTP treatment options
5. Physicians and patients have access to ACCELANYL
6. Sufficient resources secured & aligned across internal departments
7. Minimize risk for abuse & diversion

Organizational Implications

Objectives & Strategies
Linked to CSFs

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CSF #1: Successfully convert ACTIQ loyalists to ACCELANYL adopters within the 90 day period

Objectives:

- Achieve high level of pre-launch awareness (>90% of core ACTIQ loyalists)
- Strengthen relationships with core ACTIQ prescribers (increase in sales force call frequency among ACTIQ loyalists)

Strategies:

- Deploy Pain Care sales force Q1 2006 to handle complexity of CII selling process, increasingly competitive environment, and to ensure focused launch effort
- Deploy pain-dedicated MSLs Q1 2006
- Implement clinical experience program by April 2006
- Disseminate key differentiating ACCELANYL clinical & scientific info prior to product approval through appropriate vehicles
  - Tactics: CME, manuscripts, abstracts, posters, review articles
- Establish physician loyalty initiatives
- Establish patient loyalty initiatives

CSF#2: Continue to develop BTP market by increasing awareness & understanding of BTP & its optimal treatment (ROOs)

Objectives:

- Continue to grow ACTIQ/BTP TRx market (achieve ACTIQ TRx objectives in 2005 & 2006)
- Achieve higher level of awareness of ROO term (>50% of ACTIQ loyalists recognize ROO term)

Strategies:

- Demonstrate burden of illness of BTP & sub-optimal nature of current pharmacologic options
- Establish and differentiate a new opioid class of ROOs from SAOs
- Support & disseminate key BTP clinical info through appropriate vehicles
  - Tactics: CME, manuscripts, abstracts, posters, review articles, Tx guidelines, non-branded BTP promotional materials
- Sales force strengthened relationships with core prescribers

CSF #3: KOLS support ACCELANYL as an effective treatment for BTP

Objectives:

- PMEAB advisors participating in ACCELANYL clinical trials, pubs, MedEd
- KOLs involved in consultant/advisory meetings, ACCELANYL clinical trials, pubs, HOVs & MedEd

Strategies:

- Enhance & leverage KOL relationships
- Deploy pain-dedicated MSLs by Q1 2006

CSF #4: ACCELANYL is clearly differentiated from ACTIQ & other BTP treatment options

Objectives:

- 3039 data is included in NDA submission
- 3039 manuscript published by Q3 2006
- PK manuscripts (1026, 1027, 1028, 1029) published by Q3 2006
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Strategies:

- Negotiate optimal label which differentiates ACCELANYL to support strong promotional claims
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CSF #5: Physicians & patients have access to ACCELANYL

Objectives:

- ROO class is adopted by USP
- TBD – % of third party payers aware of ACCELANYL, % formulary approvals of targeted commercial and non-commercial plans, % claims approvals, etc.

Strategies:

- Establish comprehensive & coordinated managed markets plan
- Demonstrate burden of illness of BTP
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CSF #6: Sufficient resources secured & aligned across internal departments

Objectives:

- Clinical & Regulatory meet their milestones for NDA submission 8/31/05
- ACCELANYL promotional materials approved & ready for launch
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Strategies:

- Establish consensus among departments for optimal preparedness for ACCELANYL launch
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CSF #7: Minimize risk for abuse & diversion

Objective:

- RMP negotiations do not delay final approval of NDA
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Strategies:

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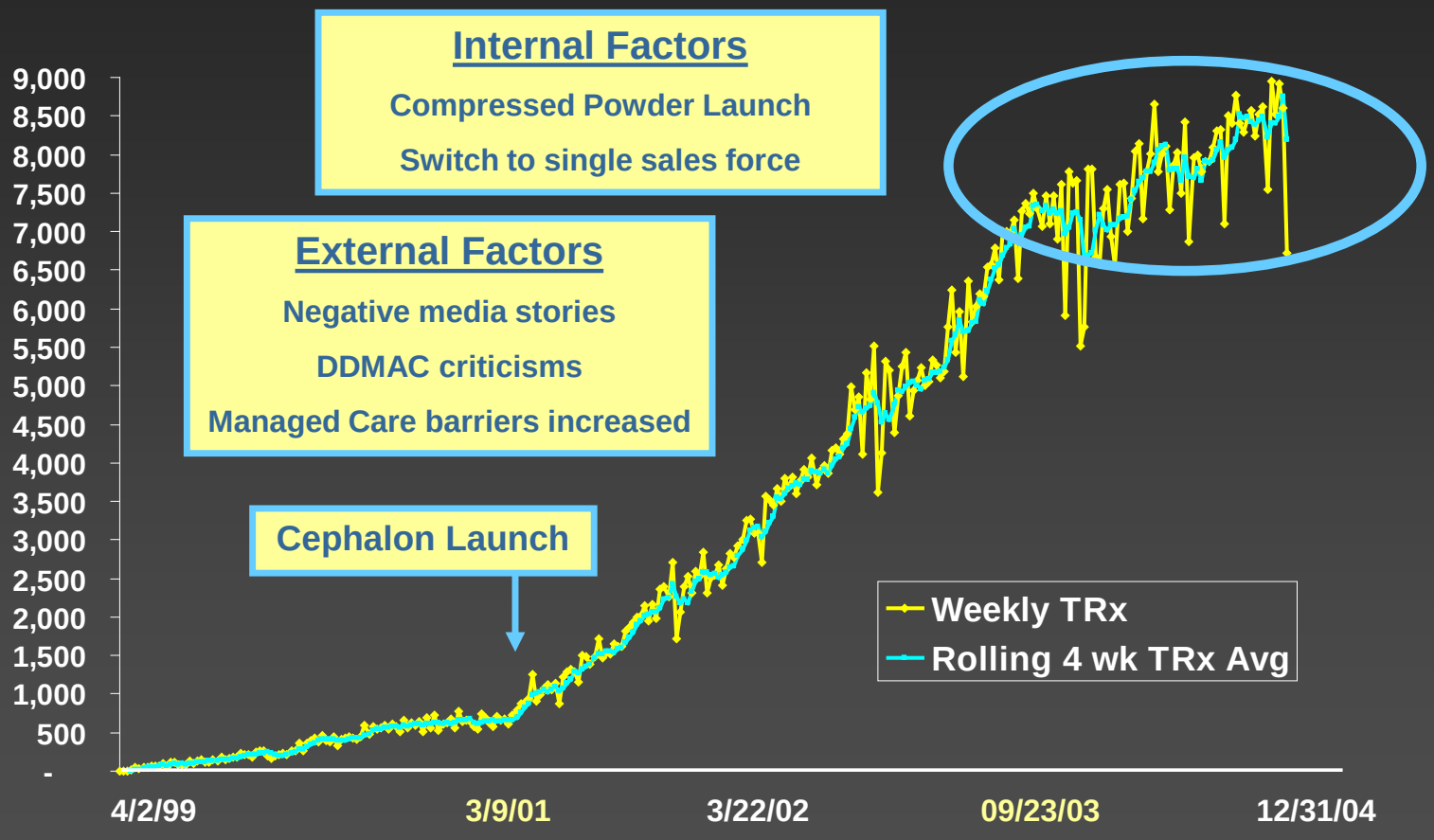

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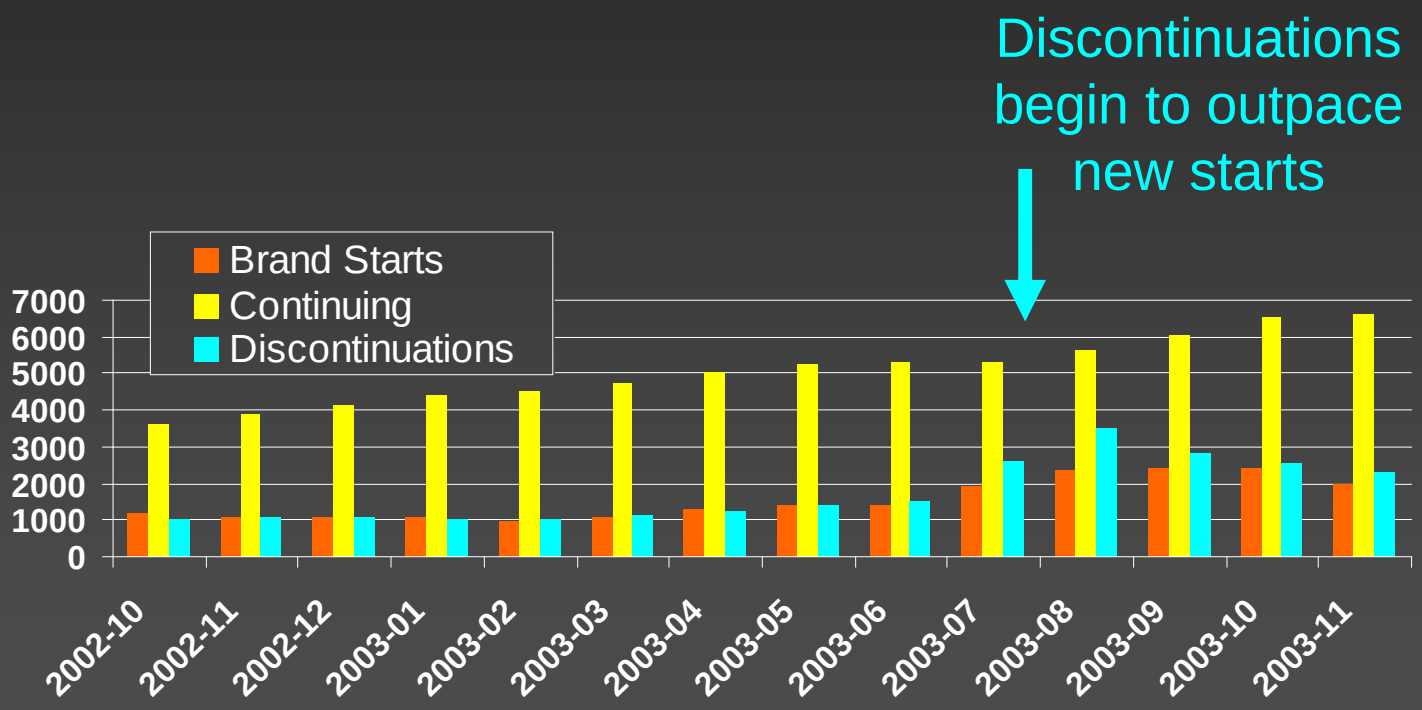

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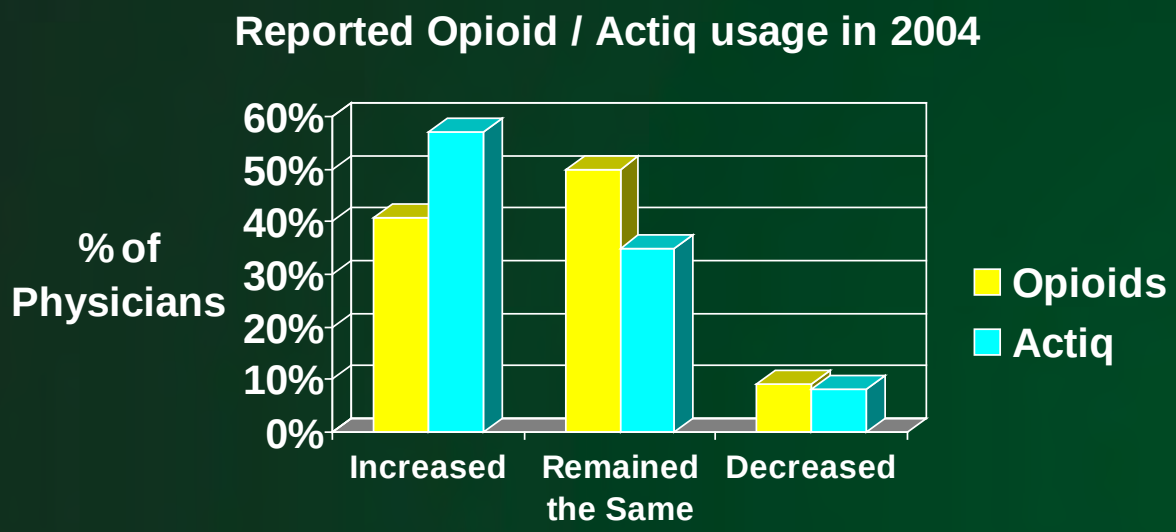

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Commercial Timeline

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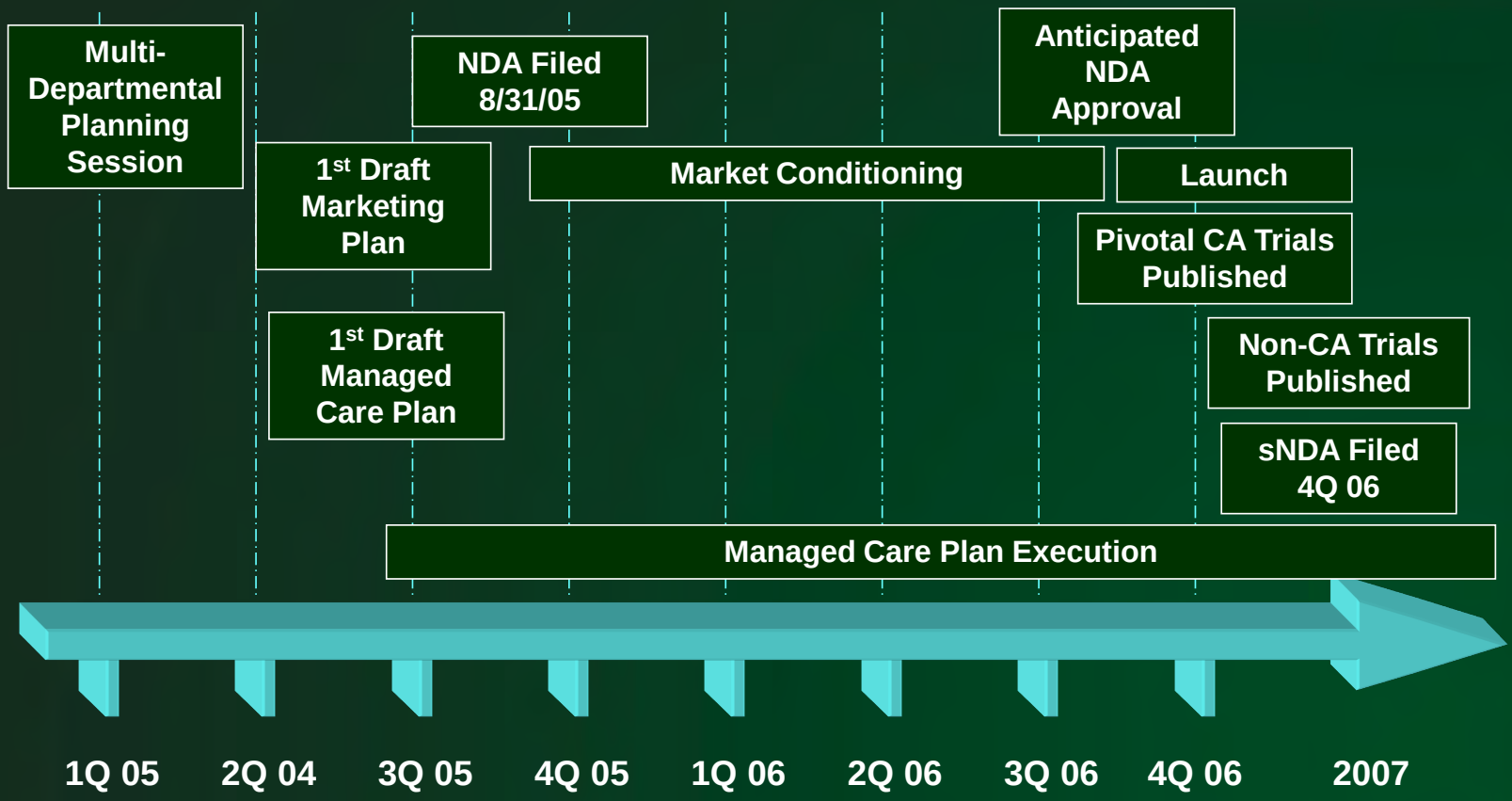

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